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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,085	06/01/2005	Michael L. King	PU4927USW	8241
23347	7590	06/27/2007		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER MITCHELL, TEENA KAY	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,085	Applicant(s) KING, MICHAEL L.	
	Examiner Teena Mitchell	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


TEENA MITCHELL
PRIMARY EXAMINER

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 6-13, 27, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Nohl et.al. (6,390,088).

Regarding claim 1, Nohl discloses a container (2) having the pharmaceutical formulation comprising at least one medicament present therein; and a mouthpiece (6) configured for oral engagement with a patient and in communication with said container, the mouthpiece (6) having an inner surface and an outer surface; wherein the outer surface of the mouthpiece contains at least one longitudinally –extending disuniformity

(7) such that when the patient orally engages the mouthpiece at least one void space is created between the outer surface of the mouthpiece and the oral cavity of the patient so as to provide an air flow channel through the at least one void space to facilitate intake of the at least one medicament by the patient (Figs. 2, 3).

Regarding claim 2, Nohl discloses wherein the at least one longitudinally-extending disuniformity is selected from the group consisting of at least one protrusion, at least one indentation, at least one opening in the outer surface of the mouthpiece (6; Figs. 1, 2).

Regarding claim 3, Nohl discloses wherein at least one longitudinally-extending disuniformity comprises a plurality of protrusions (Figs. 2, 3).

Regarding claim 4, Nohl discloses wherein the plurality of protrusions are equidistant from one another (Figs. 2, 3).

Regarding claim 6, Nohl discloses wherein the protrusions are present throughout the outer surface of the mouthpiece (Figs. 2, 3).

Regarding claim 7, Nohl discloses wherein said at least one protrusion is present as one protrusion (Figs. 2, 3).

Regarding claim 8, Nohl discloses wherein the said at least one longitudinally-extending disuniformity comprises a plurality of indentations (Figs. 2, 3).

Regarding claim 9, Nohl discloses wherein the plurality of indentations comprise two indentations present opposite to each other along opposing sides of the mouthpiece (Figs. 2, 3).

Regarding claim 10, Nohl discloses wherein the longitudinally-extending disuniformity is present as at least one opening (Figs. 2, 3).

Regarding claim 11, Nohl discloses wherein at least one opening comprises a plurality of openings (Figs. 2, 3).

Regarding claim 12, Nohl discloses wherein the plurality of openings comprises two openings each present opposite to each other on opposing sides of the mouthpiece (Figs. 2, 3).

Regarding claim 13, Nohl discloses wherein the pharmaceutical formulation comprises at least one medicament (Col. 1, lines 8-19).

Regarding claim 27, note rejections of claims 1, 2, 8, and Col. 1, lines 8-19).

Regarding claim 28, Nohl discloses activating the inhaler to deliver the at least one medicament to the patient (Col. 1, lines 8-19).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. **Ascertaining the differences between the prior art and the claims at issue.**
3. **Resolving the level of ordinary skill in the pertinent art.**
4. **Considering objective evidence present in the application indicating obviousness or nonobviousness.**

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nohl et.al. (6,390,088).

Regarding claim 5, Nohl discloses the claimed invention except for the plurality of protrusions present opposite to each other along respective sides of the mouthpiece. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the protrusions located opposite to each other along respective sides of the mouthpiece, since it has been held that rearranging of parts of an invention involves only routine skill in the art. In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

Claims 14-26 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nohl et.al. (6,390,088) in view of Rand (6,474,331).

Regarding claims 14-26 and 29-34 Nohl does not disclose the specific medicaments claimed. Rand in an inhaler teaches the limitations of the claimed medicaments, therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the claimed medicaments based upon the teachings of Rand because such medicaments are well-known in the respiratory art (Col. 9, lines 40-67 and Col. 10, lines 1-20 of Rand).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show inhaler devices: 2007/0095342.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

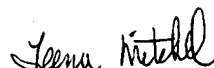
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Teena Mitchell
Primary Examiner
Art Unit 3771
June 22, 2007


TKM